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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,634	10/19/2000	Paul John Rennie	8308	8314

27752 7590 11/13/2008

THE PROCTER & GAMBLE COMPANY
Global Legal Department - IP
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EXAMINER	
CRUZ, KATHRIEN ANN	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
11/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/692,634	RENNIE ET AL.	
	Examiner	Art Unit	
	KATHRIEN CRUZ	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-7,20-22,26,27,54 and 57-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-7,20-22,26,27,54 and 57-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed July 16, 2008 has been received and entered in the application.

Action Summary

The rejection of claims 1, 4-7, 20-22, 26, 27, 54 and 57-60 under 35 U.S.C. 103(a) as being unpatentable over Diehl (EP0505374B1), in view of Makino et al. (US Patent No. 4789667) and further in view of Kuhrt et al. (Virucidal Activity of Glutaric Acid and Evidence for Dual Mechanism of Action, Antimicrobial Agents and Chemotherapy, Dec. 1984, pp. 924-927) is maintained for the reasons stated in the previous Office Action.

Response to Arguments

Applicant's arguments filed 07/16/2008 have been fully considered but they are not persuasive.

Applicant's argue that "Dissociation Constants of Organic Acids and Bases", in CRC Handbook of Chemistry and Physics, Internet Version 2007 (87th Edition) cannot be relied for support because of the date of 2007. This argument has been fully considered but has not been found persuasive because the "Dissociation Constants of

Organic Acids and Bases", in CRC Handbook of Chemistry and Physics, Internet Version 2007 (87th Edition), David R. Lide, ed., Taylor and Francis, Boca Raton, FL. pp.8-44 and 8-46 where the pKa's of pyroglutamic, glutaric and ascorbic acid are found. All are within the pKa requirement of 3.0-5.0 of the organic acids as claimed. This is included in support of the physical/chemical properties of the compounds.

The applicant's have stated that the CRC handbook quoted above can not be used as the date is not before the file date of 10/19/2000. The examiner respectfully points out that this reference book has been utilized to provide physical/chemical properties of claimed compounds (i.e. organic acids), as such the date is irrelevant as it is not what the rejection is based upon but only to indicate the properties as non-patentable inherent properties. The examiner will note that the CRC handbook of chemistry and physics has been utilized and published for many decades and the properties of dissociation constants of organic acids and bases indicated above have been included for nearly the entire published life of the CRC handbook. Absent evidence to the contrary the use of this reference is valid. Further, Applicant's attention is drawn to the same reference publish in 1996 teaches the same physical/chemical properties of the claimed organic acids (see pages 3-15, 3-173). This reference show that the chemical/physical properties of a compound do not change over time.

Applicants argue that Makino fails to teach or suggest a method for treating the cold or influenza viruses wherein the method comprises the step of spraying into the nasal turbinates a composition comprising: from about 1% to about 20% pyroglutamic acid and from about 0.01% to about 10% organic acid having a dissociation constant

(pKa) value from about 3.0 to about 5.0 and a pH adjusting agent; wherein said composition has a pH of less than 4.5; wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues. This argument has been fully considered but has not been found persuasive because Makino et al teaches a pharmaceutical composition of pyroglutamic acids(10% by weight) for nasal cavity of a warm blooded animal (claim 12). Therefore, this reference teaches the employment of pyroglutamic acids for nasal pharmaceutical is well known in the art.

Applicant's argue that Kuhrt does not teach or suggest a homogeneous solution that has a pH of 3.5 to about 5.5 on the nasal tissue. This argument has been fully considered but has not been found persuasive because the combined references teach the equivalent compounds as claimed and that properties such as pKa and pH are inherent to the organic acids (ascorbic acid-Vitamin C-pKa=4.21) and solutions themselves. Moreover, Kuhrt teaches that rhinoviruses as a group are notable sensitive to inactivation in solutions with a pH of less than 5.3. Further it is simple routine optimization to adjust pH for one of ordinary skill in the art as presented in the last office action. Therefore, one of ordinary skill in the art would reasonably expect that Diehl's composition as modified by Makino and in view of Kuhrt would be effective in treating a cold or influenza viruses.

Applicant's argue that "assuming arguendo that one having ordinary skill in the art would combine the disclosures .....one would still fall short of the of Applicants' claimed invention only to arrive at a composition that comprises vitamin C, glutaric acid

and zinc that utilizes pyroglutamic acid to enhance drug delivery and inactivates RV-14 and several other strains of human rhinoviruses by a mode of action independent of acidic pH at low temperatures". This argument has been fully considered but has not been found persuasive because the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In close, it is clear that the active compounds pyroglutamic acid and organic acids are useful in the treatment of colds (e.g. viruses) in view of Diehl.

In view of the above, the Office Action of January 25, 2008 is deemed proper and repeated herein for Applicants' convenience.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4-7, 20-22, 26, 27, 54 and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diehl (EP0505374B1), in view of Makino et al. (US Patent No. 4789667) and further in view of Kuhrt et al. (Virucidal Activity of Glutaric Acid and Evidence for Dual Mechanism of Action, Antimicrobial Agents and Chemotherapy, Dec. 1984, pp. 924-927), all of record.

Diehl teaches, on page 2, a pharmacological composition for treatment of the common cold by spraying said composition into the oral cavity (with mucosal absorption of the

composition posited as the means of administration). The composition comprises vitamin C (ascorbic acid) and a non-toxic zinc salt. In example I Table 1 Diehl teaches a suitable zinc-vitamin C composition that includes pharmaceutical grade water, ascorbic acid (1.64% by weight), sodium bicarbonate (0.14% by weight), glycerine, potassium sorbate, EDTA, zinc gluconate (1.09% by weight), L-lysine, glycine, fruit juice, sucrose, magnasweet, tween-80, trace bioflavonoids, orange flavoring and peppermint oil.

Diehl does not teach direct spraying of the composition into the nasal turbinates, • or the use of pyroglutamic acid in the composition.

Makino et al. teach, in the abstract, a pharmaceutical composition for external use with enhanced penetration of a pharmacologically active agent through the skin or mucosa, said composition comprising a pharmacologically active agent and an optically active or inactive pyroglutamic acid ester.

In col. 3 lines 55-65, Makino et al. teach that in US Patent No. 4434159 a drug which is substantially unabsorbable through the mucosa of the rectum is made absorbable through the rectal mucosa by co-administration with a penetration enhancer (pyroglutamic acid or a salt thereof). Makino et al. teach, in col. 12 lines 17-40, that the compositions contain the penetration enhancer in an amount of from 0.2-25% by weight, preferably 0.5-12% by weight based on the total weight of the composition. Further the mucosa may be that of the rectum, oral cavity, nasal cavity or vagina.

Makino et al. teach, in col. 14 line 1 to col. 15 (table 2 comparison 16 and 17), ointments prepared from 1 part of nifedipine, 10 parts L-pyroglutamic acid (comparison 1) or 10 parts DL-pyroglutamic acid (comparison 2), 89 parts of a gel ointment base (composed

of 1 part of Carbopol 934-a mucoadhesive agent as defined in the current specification page 8 lines 1-10, 12 parts of propylene glycol, 30 parts ethanol, 1 part diisopropanolamine and 56 parts water). Thus the penetration enhancer (L-pyroglutamic acid or DL-pyroglutamic acid) is present in 10% by weight, the Carbopol 934 is present in 1% by weight, and the pharmacologically active agent is present in 1% by weight.

Kuhrt et al. teach, in the abstract, that Rhinoviruses as a group are notably sensitive to inactivation in solutions with a pH of less than 5.3: On page 924, Kuhrt et al. teach that glutaric acid (one of the organic acids currently claimed) has been demonstrated as an effective virucidal agent against rhinovirus on human skin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the ointment composition of Makino et al. comprising a penetration enhancer (pyroglutamic acid) and ointment base (that could be applied to mucosa of the rectum, oral cavity, nasal cavity or vagina), with the pharmacological composition of Diehl comprising ascorbic acid and zinc gluconate in order to formulate a 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 Fi2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claims allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN CRUZ whose telephone number is (571)270-5238. The examiner can normally be reached on Mon - Thurs 7:00am - 5:00pm with every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KATHRIEN CRUZ/
Examiner, Art Unit 1617

/JENNIFER M KIM/

Primary Examiner, Art Unit 1617